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Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED
PHARMACEUTICAL PRODUCTS
R&D, INC., NORTON
(WATERFORD) LTD., and TEVA
PHARMACEUTICALS USA, INC.

Plaintiffs,

V.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

DECLARATION OF REBEKAH CONROY

- I, Rebekah Conroy, of full age, hereby declare as follows,
- 1. I am an attorney at law of the State of New Jersey, a member of good standing of the bar of this Court, and a Member of the law firm Stone Conroy

LLC, co-counsel to Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Defendants"). The matters set forth herein are based on my personal knowledge.

- 2. I submit this declaration in support of Defendants' Consolidated Brief in Support of Defendants' Rule 12(c) Motion and in Opposition to Plaintiffs' Motion to Dismiss, filed concurrently herewith.
- 3. Attached as Exhibit 1 is a true and correct copy of excerpts from Merriam-Webster's Collegiate Dictionary (10th ed. 2002).
- 4. Attached as Exhibit 2 is a true and correct copy of excerpts from Merriam-Webster's Collegiate Dictionary (11th ed. 2020).
- 5. Attached as Exhibit 3 is a true and correct copy of Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36(2) Nature Biotechnology 142-45 (Feb. 2018), available at https://www.nature.com/articles/nbt.4078.epdf?author_access_token=k19w_aka6y https://www.nature.com/articles/nbt.4078.epdf https://www.nature.com/articles/nbt.4078.epdf https://www.nature.com/articles/nbt.4078.epdf https://www.nature.com/articles/nbt.4078.epdf <a href="https://www.nature.com/articles/nbt.40
- 6. Attached as Exhibit 4 is a true and correct copy of a Food and Drug Administration Guidance Document titled *Reviewed Guidance for Nebulizers*,

Metered Dose Inhalers, Spacers and Actuators (Oct. 1993), available at https://www.fda.gov/media/72312/download (last accessed Feb. 20, 2024).

- 7. Attached as Exhibit 5 is a true and correct copy of the Federal Trade Commission's ("FTC") Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sep. 14, 2023), available at https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement0 92023.pdf (last accessed Feb. 20, 2024).
- 8. Attached as Exhibit 6 is a true and correct copy of the FTC's brief as *amicus curiae* in *Mylan Pharms Inc. v. Sanofi-Aventis U.S. LLC*, Civil Action No. 23-836 (W.D. Pa.), filed Nov. 20, 2023 as D.I. 61-3.
- 9. Attached as Exhibit 7 is a true and correct copy of excerpts from Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.'s Proposed Pretrial Findings of Fact in *Teva Branded Pharm. Prod. R&D, Inc. v. Cipla Ltd.*, Civil Action No. 20-10172 (D.N.J.) (consolidated), filed June 12, 2023 as D.I 283.
- 10. Attached as Exhibit 8 is a true and correct copy of H.R. Rep. No. 116-47 (2019), available at https://www.congress.gov/116/crpt/hrpt47/CRPT-116hrpt47.pdf (last accessed Feb. 20, 2024).
- 11. Attached as Exhibit 9 is a true and correct copy of the Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 (Jan. 5, 2021),

available at https://www.congress.gov/116/plaws/publ290/PLAW-116publ290.pdf (last accessed Feb. 20, 2024).

- 12. Attached as Exhibit 10 is a true and correct copy of excerpts from Congr. Rec. Vol. 166, No. 206 (SA 2693) (Dec. 7, 2020) (available at https://www.congress.gov/116/crec/2020/12/07/166/206/CREC-2020-12-07.pdf (last accessed Feb. 20, 2024).
- 13. Attached as Exhibit 11 is a true and correct copy of excerpts from H.R. Rep. No. 108-391 (2003), available at https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf (last accessed Feb. 20, 2024).
- 14. Attached as Exhibit 12 is a true and correct copy of excerpts from 68 Fed. Reg. No. 116 (June 18, 2003), available at https://www.govinfo.gov/content/pkg/FR-2003-06-18/pdf/03-15065.pdf (last accessed Feb. 20, 2024).

I hereby declare under the penalty of perjury that the foregoing statements made by me are true and correct.

Dated: February 20, 2024 /s/ Rebekah Conroy
Rebekah Conroy